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UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

IN RE:	:	
Fosamax Products Liability Litigation	:	1:06-md-1789 (JFK)
	:	
This Document Relates to:	:	
	:	
Boles v. Merck & Co., Inc.	:	
Case No: 1:06-cv-09455-JFK	:	

DEFENDANT MERCK & CO., INC.'S
MEMORANDUM IN SUPPORT OF ITS
POST-TRIAL MOTION FOR JUDGMENT AS A MATTER OF LAW

Defendant Merck & Company, Inc. ("Merck"), by its attorneys, files this memorandum in support of its Post-Trial Motion for Judgment as a Matter of Law, pursuant to Rule 50(b) of the Federal Rules of Civil Procedure. Plaintiff's only remaining claims in this case are based upon theories of failure to warn and design defect, under strict liability and negligence causes of action. In its instructions to the jury, the Court set forth each of the elements that Plaintiff must satisfy before she is entitled to any recovery. Plaintiff has failed to present evidence that could justify a jury verdict in her favor under any of her claims, and Merck is entitled to judgment as a matter of law for each of these reasons:

- Plaintiff cannot prevail on a failure to warn claim unless she can show that an alleged *failure to warn* of a product risk proximately caused her to suffer the injury that should have been warned about. There is no evidence in the record from which a reasonable juror could find that a warning about ONJ would have changed the decision of Mrs. Boles' physician to prescribe Fosamax.

- Plaintiff's failure to warn claims also fail as a matter of law because no reasonable juror could conclude that Merck "knew or should have known" that Fosamax created a risk of ONJ or that it was "known or knowable" that Fosamax created such a risk *before October 2003*. Dr. Parisian was the only expert proffered by Plaintiff to testify on this issue, but she never testified that Merck should have known about ONJ before October 2003; she based her testimony on a mere handful of post-marketing adverse event reports (none of which referenced ONJ or its physical characteristics of exposed, dead bone); and she has no qualifications to opine as to what Merck should have known during that time frame.

- Plaintiff's design defect claims fail because she has introduced no competent evidence to support any verdict that Fosamax is "unreasonably dangerous" or that the alleged risks of Fosamax outweigh its benefits.

- Plaintiff's negligent design defect claim fails because, in addition to failing to prove any design defect, she has introduced no evidence whatsoever of *negligence* in the design of Fosamax.

- All of Plaintiff's claims fail for lack of causation because she has not introduced evidence from which a reasonable juror could conclude that she had ONJ before October 1, 2003.

For all of these reasons, Merck is entitled to judgment as a matter of law pursuant to Rule 50(b).

ARGUMENT

Judgment as a matter of law should be entered under Rule 50(b) when a plaintiff has failed to introduce sufficient evidence upon which a reasonable juror could decide in her favor. This is the same standard used to determine whether summary judgment is appropriate. *United States v. Real Property Known As 77 East 3rd Street*, 869 F. Supp. 1042, 1056 (S.D.N.Y. 1994) (stating that, when "assessing post-trial motions for judgment as a matter of law, district courts apply the same standard used in assessing whether factual issues exist as used in reviewing summary judgment motions"). To avoid judgment as a matter of law, the Plaintiff "must offer 'concrete evidence from which a reasonable juror could return a verdict in his favor.'" *Id.* (quoting *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 256 (1986)); *see also Gillaizeau v. Mitchelson*, 1985 WL 216, *4 (S.D.N.Y. Jan. 24, 1985) (Keenan, J.) (party opposing summary judgment "must supply concrete evidence to place the facts in dispute"); *County of Suffolk v. Long Island Lighting Co.*, 907 F.2d 1295, 1318 (2d Cir. 1990) (party opposing judgment as a matter of law cannot rely on "unreasonable inferences" or "inferences at war with undisputed facts").[1] Plaintiff cannot meet this standard with respect to any of her remaining failure to warn or design defect claims.

I. PLAINTIFF'S FAILURE-TO-WARN CLAIMS FAIL AS A MATTER OF LAW.

Plaintiff's strict liability and negligence claims based upon failure to warn each require the Plaintiff to establish that a warning should have been given prior to her alleged injury, and

[1] Under Rule 50(b), entry of judgment as a matter of law is appropriate after trial and after a mistrial based on a hung jury. *See Hathaway v. Coughlin*, 37 F.3d 63, 64 (2d Cir. 1994) (reviewing merits of Rule 50(b) motion filed after mistrial due to deadlocked jury); *see also Gonzalez Perez v. Gomez Aguila*, 312 F. Supp. 2d 161, 164 (D.P.R. 2004).

that this lack of a warning was the proximate cause of her injury. (Jury Charge 27, 30, 32-33.) Plaintiff cannot establish either of these elements with respect to her strict liability or her negligence claims.

A. There Is No Evidence That A Failure To Warn About The Risk Of ONJ Caused Plaintiff's Alleged Injury.

Plaintiff has introduced no evidence to show that she would not have taken Fosamax if a warning about ONJ had been included on the Fosamax label. While Merck has raised this issue at several points in this proceeding, the Court has now articulated the governing Florida law that applies to Plaintiff's claims, and Merck respectfully submits that the Court's prior ruling on Merck's Rule 50(a) Motion is not consistent with this governing law. The Court's jury instructions establish that, in order to prevail on a failure to warn claim under Florida law, Plaintiff must prove that Merck failed to provide a warning about the safety risk from which Plaintiff claims to have suffered (here, ONJ), and that the resulting injury was proximately caused by this missing warning. Specifically, the Court instructed the jury that "Plaintiff alleges that Merck failed to warn her prescribing physician, Dr. Mills, that Fosamax presents a risk of ONJ, that *Merck's failure to warn about this risk affected Dr. Mill's prescribing decision*, and that Plaintiff's use of Fosamax resulted in her developing ONJ." (Jury Charge 27 (emphasis added).) The Court further instructed the jury that, whether under a theory of negligence or strict liability, Plaintiff must prove that "Merck's failure to warn *about the risk of ONJ* was a 'legal cause' of Plaintiff's injury." (Jury Charge 30, 33 (emphasis added).)[2]

[2] This jury charge is fully supported by Florida law. *See Baker v. Danek Med.*, 35 F. Supp. 2d 875, 881 (N.D. Fla. 1998) ("a plaintiff must not only show that a manufacturer's warning was inadequate, but that such inadequacy affected the prescribing physician's use of the product and thereby injured the plaintiff"); *Walls v. Armour Pharm. Co.*, 832 F. Supp. 1505, 1514 (M.D. Fla. 1993) (in infected blood products case, court properly instructed jury that plaintiff had burden to prove that "[defendant's] negligence was a proximate cause of [plaintiff's] injuries; that is, had [defendant] provided such a warning [to plaintiff's physician], [plaintiff] would not have been infected"), *aff'd in part, reversed and remanded in part on other grounds sub nom., Christopher v. Cutter Labs.*, 53 F.3d 1184 (11th Cir. 1995). Plaintiff excepted only to the timing aspect of the jury charge,

In denying Merck's original motion under Rule 50(a), the Court recognized that Plaintiff did not present any evidence, including any testimony by Dr. Mills (Plaintiff's prescribing physician) to show that addition of a warning related to ONJ would have altered Dr. Mills' decision to prescribe Fosamax for the Plaintiff. (*See* Trial Tr. 1625, Aug. 24, 2009 (noting Court's comment "Now what did [Dr. Mills] say about ONJ and risk? I can't find anything in the record that he said about ONJ and risk. I looked at his testimony.").) Despite the absence of any such evidence, the Court denied Merck's Rule 50(a) motion on the theory that a jury might conclude that "Merck's failure to provide *all information regarding the risks and benefits associated with Fosamax* was a proximate cause of the plaintiff's injury." (*Id.* 1630.) Merck respectfully submits that an alleged "failure to provide all information" is not the correct legal standard to determine whether a plaintiff can prove proximate cause under a failure to warn theory of recovery. Rather, as the jury instructions state, where Plaintiff claims to have suffered a specific injury on account of using a drug, Plaintiff must show that a warning *about that injury* would have made a difference in her physician's decision to prescribe the drug. Plaintiff cannot base a "failure to warn" claim upon an alleged lack of efficacy information or alleged missing warnings that are wholly unrelated to Plaintiff's injuries.

Plaintiff has no evidence to show that an alleged missing warning about ONJ caused her injury. Lacking such evidence, Plaintiff instead seeks to conflate her failure to warn claim with other causes of action based upon design defects or misrepresentation. A failure to warn claim does *not* involve or permit balancing of the risks and benefits of a product. As the Court's jury instructions recognize, such issues are addressed by Florida law under a design defect claim. Nor can Plaintiff base a failure to warn claim upon allegations that a company sales

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but not to any of the elements of the charge stated above, and Plaintiff cannot now object to the legal principles set forth therein.

representative allegedly overstated the benefits of a product, as Plaintiff argued at trial. Such an argument would only be relevant to a claim for misrepresentation or fraud, not a failure to warn claim, and all misrepresentation or fraud claims in this case have been dismissed by the Court.

Plaintiff's inability to prove a proper failure to warn claim is illustrated by her closing arguments to the jury, which actually contradicted the Court's jury instructions. Plaintiff made no effort to show that a warning about ONJ would have made any difference, but instead repeatedly referred to "risk versus benefit" and contended that failure-to-warn liability could be premised on alleged overstatements as to the benefits of Fosmax. (*See, e.g.*, Trial Tr. 2498, Sept. 2, 2009 (contending that "there's two rules. We've talked about the lack of benefit; don't overstate the benefit of your drugs. Next is disclose the potential harms of this drug. And again, *either one of these rules is the basis for liability in this case. You don't have to find that both rules were violated*") (emphasis added).)[3] Plaintiff even went so far as to argue that, if Merck overstated the benefits of Fosamax, any warning about ONJ would be *irrelevant*. (*Id.* 2504 (contending that "if they overstated the benefit" then "[i]t doesn't matter what they knew about ONJ").)[4] Plaintiff twisted the elements of "failure to warn" so far beyond recognition that she actually argued that Merck could be held liable for "failure to warn" even if there was no missing warning. In other words, with no evidence to prove that a missing warning about ONJ caused her injury, Plaintiff improperly sought to change her cause of action into one for alleged *misrepresentation*.

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[3] *See also* Trial Tr. 2483, Sept. 2, 2009 (contending "what is the risk versus the benefit . . . that's what this case is about").

[4] This argument by the Plaintiff would seemingly render moot almost the entirety of the testimony of Drs. Parisian and Furberg. If Plaintiff were correct, her "failure to warn" claims need not identify a warning related to her injury, need not show that any such warning should have been given, and need not require any showing as to whether or when such a warning would be appropriate. In short, Plaintiff seeks to craft for herself a new cause of action utterly divorced from the doctrines of "failure to warn" that are well recognized in products liability law.

As the Court's jury instructions recognize, a failure to warn claim, whether presented under theories of negligence or strict liability, is a particular cause of action under which Plaintiff must prove that she should have been warned of the harm that forms the basis for her lawsuit (here, ONJ), and that the lack of such warning caused her injury. (Jury Charge 27, 30, 32-33.) *See also, e.g., Colville v. Pharmacia & Upjohn Co.*, 565 F. Supp. 2d 1314, 1320 (N.D. Fla. 2008) (noting that a necessary element of negligent and strict liability failure to warn cases in Florida is "that the inadequacy of the warnings proximately caused the Plaintiff's injury"). Plaintiff introduced no evidence whatsoever to show that any lack of a warning caused her injury, and even omitted from Dr. Mills' testimony the weak assertions upon which the Plaintiff relied in opposing summary judgment. Judgment should be entered as a matter of law on Plaintiff's failure to warn claims.[5]

B. Dr. Parisian's Testimony Does Not And Cannot Prove That Merck Should Have Known That Fosamax Presented A Risk Of ONJ Before October 2003.

Judgment also should be entered as a matter of law on Plaintiff's failure to warn claims because Dr. Parisian presented the only expert testimony proffered by Plaintiff to show that Merck should have provided a warning related to ONJ, and Dr. Parisian's testimony falls far short of the proof required by the Court's jury instructions. As the Court instructed the jury, Plaintiff's claim of negligent failure-to-warn required her to prove that "[b]y October 2003, Merck knew or through the exercise of reasonable care should have known that Fosamax created a risk of ONJ." (Jury Charge 30.) Plaintiff's claim of strict liability failure-to-warn similarly required proof that "[b]ased on the generally recognized and best scientific and medical

[5] Plaintiff has also argued that she does not need to introduce evidence to prove causation and that the jury should be given a heeding presumption. (Trial Tr. 1625, 1628, Aug. 24, 2009.) The Court properly denied the Plaintiff's request for such an instruction, as it is not consistent with Florida law. Florida requires a Plaintiff to *prove* causation – it cannot be presumed.

knowledge available by October 2003, it was known or knowable that Fosamax created a risk of ONJ." (Jury Charge 32.) Plaintiff was required to make this showing through expert testimony. *Giles v. Wyeth*, 500 F. Supp. 2d 1063, 1067 n.4 (S.D. Ill. 2007) ("What a drug manufacturer knew or should have known is a question of fact, which a plaintiff must establish by expert testimony.").[6] Dr. Parisian, however, never testified that Merck should or could have known that Fosamax created a risk of ONJ before October 2003, or that Merck had a duty to warn about ONJ before that time.

1. Plaintiff Cannot Rely Upon Dr. Parisian's Bald Conclusion That Merck Should Have Put "Risk Information" In Its Label.

Dr. Parisian did not testify that Merck should have provided a *warning* that Fosamax could cause ONJ prior to October 2003, and she has no reasonable evidence or analysis upon which such a conclusion could be based. Dr. Parisian instead skirted this issue by presenting a conclusory opinion that Merck should have "changed its label" to reflect "risk information," such as by including a reference to an adverse event report. (Trial Tr. 1133-34, Aug. 19, 2009.) Such assertions should be rejected for the same reason her conclusory testimony was rejected by the *Prempro* MDL Court, in granting a motion under Rule 50(b). *See In Re Prempro Prods. Liab. Litig.*, 554 F. Supp. 2d 871, 887 (E.D. Ark. 2008) (granting Rule 50(b) motion where "Dr. Parisian testified as to the bottom line without any explanation [and] failed to provide expert analysis"). As the *Prempro* Court observed, Dr. Parisian's conclusory testimony "reveals how vital it is that judges not be deceived by the assertion of experts who offer credentials rather than

[6] *See also In re Fosamax Prods. Liab. Litig.*, __ F. Supp. 2d __, Nos. 1:06-09455, 1:06-1789, 2009 WL 2431535, *7 (S.D.N.Y. Aug. 5, 2009) (noting that expert testimony is required to establish the inadequacy of the drug label); *Upjohn Co. v. MacMurdo*, 562 So.2d 680, 683 (Fla. 1990) (whether prescription drug manufacturer failed to adequately warn of drug side effect must be proven through expert testimony). The interpretation of adverse event reports, in particular, is an area well outside the expertise of a lay jury and must be based on testimony from an expert witness. Adverse event reports are frequently not verified, are intended by design to include reports for events with no relationship to the drug that is being tested or sold, frequently lack significant detail or are based on hearsay, and require interpretation as to the significance of the number and type of such reports in any given case in comparison to the frequency with which a drug is used.

analysis." *Id.*[7] Dr. Parisian's conclusions alone, without any reliable factual basis, fall well short of "concrete evidence from which a reasonable juror could return a verdict in [Plaintiff's] favor." *Real Property Known As 77 East Third Street*, 869 F. Supp. at 1056.

2. No Reasonable Juror Could Conclude That Merck Should Have Known Of An Alleged Relationship Between ONJ And Fosamax Based On The Few Adverse Event Reports Cited By Dr. Parisian.

Dr. Parisian's opinions are wholly inadequate to support any claim that Merck should have either been aware of any relationship between Fosamax and ONJ or that any warning about ONJ should have been included on the Fosamax label before October 2003. Dr. Parisian contended only that (1) a single case of *osteomyelitis*, not ONJ, was reported in 1995 among thousands of Fosamax patients in a pre-marketing clinical trial of Fosamax; and (2) that Merck received in the late 1990's a handful of post-marketing reports of "oral-related" adverse events, such as exostosis, that did not refer to non-healing exposed necrotic bone or to ONJ. (Trial Tr. 1122, 1127-28, Aug. 19, 2009.) Dr. Parisian also conceded that the very term "ONJ" did not exist before October 2003. (Trial Tr. 1122, Aug. 19, 2009.) Dr. Parisian never testified that, before October 2003, Merck should or could have known, based upon these few reports, that ONJ was a cognizable condition, let alone that Fosamax use created a risk of ONJ. Nor did Dr. Parisian testify that any additional investigation of these few reports would or could have led Merck to determine that Fosamax created a risk of ONJ before October 2003.

Dr. Parisian offered no details of the few adverse event reports upon which she relied, and presented no analysis of them. There is an obvious reason why she did not do so: No

[7] *See also In Re Human Tissue Prods. Liab. Litig.*, 582 F. Supp. 2d 664, 668 (D.N.J. 2008) (finding Dr. Parisian's opinion to be "pure speculation and unsupported by any reliable scientific or medical evidence"); *Reece v. AstraZeneca Pharms., Inc.*, 500 F. Supp. 2d 736, 745 (S.D. Ohio 2007) (finding that "Dr. Parisian failed to demonstrate that she used scientifically valid methodology or reasoning in reaching her conclusions").

reasonable juror could conclude, on the basis of the reports Plaintiff submitted into evidence, that Merck should have included a warning about ONJ in the Fosamax label prior to October 2003:

- The evidence in the case actually contradicts any claim that Merck should have known that Fosamax could cause ONJ prior to October 2003. Dr. Marx testified that his September 2003 article actually stated that there was *no association* between oral bisphosphonates used to treat osteoporosis and ONJ. (Trial Tr. 1526-27, Aug. 21, 2009.) Dr. Marx agreed that, when he wrote this article he used "every medical resource [he] felt would assist [him] in guiding [his] readers accurately." (*Id.* 1528.)

- The number of events cited by Dr. Parisian was miniscule. Throughout the entire trial, Plaintiff presented only six reports on the issue of notice (out of literally millions of Fosamax prescriptions), including five post-marketing reports and one clinical trial report. Plaintiff did not, and could not, show that these six reports were sufficiently numerous to provide Merck with any information to show a relationship between Fosamax and ONJ.[8]

- The single case of osteomyelitis reported in a Fosamax patient during a clinical trial could not lead Merck to believe there was even an increased frequency of osteomyelitis (let alone ONJ), given that a second case of osteomyelitis was reported in a *placebo* patient. Incredibly, Dr. Parisian was not even aware of the report of osteomyelitis in a placebo patient when she testified. (Trial Tr. 1213-1216, Aug. 18, 2009.)

- The Fosamax patient with osteomyelitis did not have exposed bone, necrotic bone or delayed healing, and in fact the patient's condition healed in a few months. (*Id.* 1210-13.) Given Plaintiff's own definition of "BONJ" as a condition that requires non-healing, exposed necrotic bone, this report of osteomyelitis obviously does not support the Plaintiff's case.

- Two of the other five "oral-related" adverse events reports involved nothing more than gum discoloration, and there was no evidence that these patients suffered any bone problems. (Trial Tr. 875-76, Aug. 18, 2009; Pl. Ex. 1.2640; Pl. Ex. 1.2637.)

- Only three of the adverse event reports involved exposed bone, and none indicated that the exposed bone was necrotic or that healing was delayed. One of these reports stated that the patient's condition was healing (Pl. Ex. 1.0970), and another stated that at the time of the report "the patient did

[8] Dr. Parisian conceded that no FDA regulation requires that a drug's label list every adverse event reported in pre-marketing clinical trials. (Trial Tr. 1248, Aug. 20, 2009.) Any effort to report every adverse event would wholly undermine any real or significant warnings by burying them amidst a volume of worthless minutia.

not have pain," (Pl. Ex. 1.2634 at 2). The third was diagnosed as exostosis, which the jury learned is a "benign bone growth" and a "common event." (Trial Tr. 874-75, Aug. 19, 2009; Pl. Ex. 1.0922B.)

As a matter of law, such a miniscule number of adverse event reports (of no or marginal relevance) is insufficient to prove that Merck should have known of a risk of ONJ or that such risk was knowable. *See Stupak v. Hoffman-La Roche, Inc.*, 326 Fed. App'x 533, 560 (11th Cir. June 10, 2009) ("Seventeen such inconclusive case reports (out of millions of Accutane prescriptions) is simply insufficient to support an allegation that Roche knew or should have known that Accutane could cause suicide without premonitory symptoms."). No reasonable juror could conclude that Merck should have known of an alleged relationship between ONJ and Fosamax based upon these six adverse event reports (out of millions of patients). Indeed, Dr. Parisian agreed that one "can't draw any conclusions from" adverse event reports, (Trial Tr. 1223, Aug. 20, 2009),[9] and even Dr. Furberg conceded that a "responsible manufacturer" would not act unless there have been "more than a few events" of the condition at issue," (Trial Tr. 939, Aug. 18, 2009.)

3. Dr. Parisian's Assertions As To What Merck Should Have Known Are Outside The Scope Of Her Expertise.

In addition to the fact that her opinions are unsupported by any relevant facts, Dr. Parisian plainly is not qualified to opine about what, if any, action Merck should have taken in light of the few post-marketing adverse event reports at issue.[10] This Court ruled that Dr.

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[9] This Court and others have recognized the FDA's "caveats regarding the unreliability of adverse event reports," including that such reports "contain information that has not been scientifically or otherwise verified," that reported conditions may result from "other medications being taken, or even by chance," and that "accumulated case reports cannot be used to calculate incidence *or estimates of drug risk*." *In Re Bayer AG Secs. Litig.*, No. 03-1546, 2004 WL 2190357, *3 (S.D.N.Y. Sept. 30, 2004) (emphasis added); *see also In Re Baycol Prods. Litig.*, 532 F. Supp. 2d 1029, 1039 (D. Minn. 2007); 21 C.F.R. § 314.80(k) (the existence of an AER "does not necessarily reflect a conclusion . . . that the drug caused or contributed to an adverse effect").

[10] Dr. Parisian's lack of qualification is illustrated by her nonsensical assertion that "you don't typically expect to see adverse events appearing in clinical trials," (Trial Tr. 1124, Aug. 19, 2009.) In fact, adverse events in clinical trials are so common that the FDA has detailed regulations to address them, and Dr. Furberg has

Parisian was qualified only "to offer testimony about *regulatory requirements* relating to the development, testing, marketing, and surveillance of prescription drugs." (Daubert Op. & Order 57 (emphasis added). (*See also id.* 59 ("Dr. Parisian's assessment of the reasonableness of Merck's conduct in light of her experience and her understanding of FDA regulations will be helpful to the jury.").) Dr. Parisian's testimony goes far beyond regulatory requirements (such as whether or when Merck must make a report to the FDA), however, when she asserts that these six adverse event reports constitute evidence that Fosamax causes ONJ.

She has no relevant qualifications for her analysis. Her medical degree cannot, by itself, qualify her to opine on the significance of any adverse event report, where she has no expertise in the specific medical area. *See Whiting v. Boston Edison Co.*, 891 F. Supp. 12, 24 (D. Mass. 1995) ("Just as a lawyer is not by general education and experience qualified to give an expert opinion on every subject of the law, so too a scientist or medical doctor is not presumed to have expert knowledge about every conceivable scientific principle or disease."). Dr. Parisian has not practiced medicine or treated a living patient in over twenty years and, when she was practicing medicine, her specialization was pathology and not dentistry, oral surgery, or bone science. (Trial Tr. 1064, 1144, Aug. 19, 2009.) She has no background or experience with the review of post-marketing adverse event reports that would qualify her to opine as to the import of such reports for drug labeling. (*See id.* 1145.)

The FDA, in fact, recognizes that *no* single doctor would be qualified to make such an analysis. As Dr. Parisian herself writes in her book, the FDA relies on staff members from multiple disciplines, working together, to analyze post-marketing safety data. Suzanne Parisian, *FDA: Inside and Out* 185 (2001) (a "multidisciplinary professional staff of physician and Ph.D.

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devoted an entire chapter of his book, *Fundamentals of Clinical Trials*, to their evaluation. (*See* Trial Tr. 891, Aug. 18, 2009.)

epidemiologists, pharmacists, and program/product managers" are responsible for "risk assessment of drugs in the postmarketing environment"); *Grundberg v. Upjohn Co.*, 813 P.2d 89, 96 (Utah 1991) (drug data is reviewed at the FDA "by physicians, pharmacologists, statisticians, and other professionals"). Dr. Parisian's lack of relevant experience would not even qualify her to work on such multidisciplinary teams, let alone perform such analyses on her own. For all of these reasons, Dr. Parisian's testimony is not sufficient to support Plaintiff's failure to warn claims.

II. PLAINTIFF'S DESIGN DEFECT CLAIMS FAIL AS A MATTER OF LAW.

A. Plaintiff Presented No Evidence From Which A Reasonable Juror Could Conclude That Fosamax Is Unreasonably Dangerous.

As with her failure to warn claims, Plaintiff improperly has sought to recast her design defect claims in terms of misrepresentation, by repeatedly asserting that Merck "overstated the benefits and understated the risks" of Fosamax. Alleged *statements* by Merck, however, are not relevant to a design defect claim, and cannot prove that Fosamax was defectively designed. As the Court instructed the jury, Plaintiff cannot prevail under a design defect theory unless she can prove, *inter alia*, that Fosamax is "unreasonably dangerous" in that "the risks of [Fosamax] outweigh its benefits." (Jury Charge 35.) Plaintiff can only make this showing through proper expert testimony. *Alvarez v. General Wire Spring Co.*, No. 8:07-1319, 2009 WL 248264, *4 (M.D. Fla. Feb. 1, 2009); *Drury v. Cardiac Pacemakers, Inc.*, No. 02-933, 2003 WL 23319650, *4 (M.D. Fla. June 3, 2003). None of Plaintiff's experts testified that Fosamax is "unreasonably dangerous" or that its risks "outweigh its benefits," and there would have been no proper basis for them to do so.

In this case, it must be presumed that Fosamax is *not* unreasonably dangerous. The FDA has repeatedly reviewed the clinical and safety data relating to Fosamax and approved the sale of

Fosamax based upon its own determination that Fosamax is *not* unreasonably dangerous. As the Court instructed the jury: "If you find that Merck complied with applicable FDA regulations at the time Plaintiff took Fosamax, then you must presume that Fosamax was not defective or unreasonably dangerous." (Jury Charge 41.) Dr. Parisian conceded that the FDA has approved Fosamax as safe and effective multiple times since 1995, (Trial Tr. 1134-35, Aug. 19, 2009); that there is no evidence that Merck failed to report any of the post-marketing adverse events to the FDA, (Trial Tr. 1224, Aug. 20, 2009); that Merck complied with its regulatory obligations to submit to the FDA annual reports, periodic safety reports, and reports regarding clinical trials, (*id.* 1245); and that FDA regulations did not require Merck to list the handful of adverse event reports identified by Dr. Parisian in the Fosamax label, (*id.* 1248). Plaintiff presented no evidence that reasonably could rebut the presumption that the FDA was correct in its determination that Fosamax is not an unreasonably dangerous medicine.

No expert testified that Fosamax should be withdrawn from the market. Plaintiff assigned her "drug safety" expert, Dr. Furberg, to evaluate the risks and benefits of Fosamax. (Trial Tr. 912, Aug. 18, 2009.) Dr. Furberg never testified that the risks of Fosamax outweighed its benefits. Instead, he agreed that Fosamax "was a good product," (*id.* 955), that the studies submitted by Merck for approval of Fosamax "were good studies that showed efficacy," (Trial Tr. 1053, Aug. 19, 2009), and that the FDA's 1995 approval of Fosamax was "sensible," (Trial Tr. 955, Aug. 18, 2009). The testimony of Plaintiff's other experts was similar.[11]

Plaintiff's design defect case is based upon contested assertions (1) that Fosamax does not reduce fractures in osteopenic women and (2) that its fracture reduction efficacy in

[11] Dr. Parisian testified that the FIT study "showed an overwhelmingly positive effect on vertebral fractures." (Trial Tr., at 1048, Aug. 19, 2009). Dr. Goss testified: "My understanding, based on numerous discussions with bone doctors, is that bisphosphonates are useful in their armamentarium of treating bone diseases." (Trial Tr. 178-79, Aug. 12, 2009.)

osteoporotic women lasts for only three years. Even if these claims were true, which they are not, none of Plaintiff's experts testified that such facts would render Fosamax an unreasonably dangerous product or that the risks of Fosamax outweigh its benefits. The evidence, in fact, is wholly to the contrary.

There is no reasonable dispute that Fosamax's effect on bone mineral density has been thoroughly tested, and that Fosamax is effective for the *prevention* of osteoporosis. *See Gehrhardt v. General Motors, Inc.*, 581 F.2d 7, 10 n.3 (2d Cir. 1978) (stating that the court should not "overlook uncontroverted evidence" when ruling on a motion for judgment); *County of Suffolk*, 907 F.2d at 1318 (stating that the court should not adopt "inferences at war with undisputed facts" (quotation omitted)). In fact, none of Plaintiff's experts refuted the fact that Fosamax is effective in preventing osteoporosis:

- As both Drs. Furberg and Parisian conceded, the FDA approved Fosamax for the *prevention* of osteoporosis (*i.e.*, the prevention of bone loss) in non-osteoporotic women in 1997. (Trial Tr. 949, 955, Aug. 18, 2009; Trial Tr. 1158, Aug. 19, 2009.)

- As Dr. Parisian agreed, osteoporosis is "a public health threat," people with osteoporosis "are at risk for having significant fractures" that can be "debilitating" or fatal, the risk of developing osteoporosis increases as the level of one's bone loss increases, (Trial Tr. 1146-47, Aug. 19, 2009), and "it's a worthy thing to try to develop a drug to treat *or prevent* osteoporosis." (*Id.* 1148 (emphasis added).)

- As Dr. Parisian conceded, the FDA's approval of Fosamax for the prevention of osteoporosis was based on two double-blind, placebo-controlled studies in postmenopausal women that demonstrated Fosamax prevented bone loss. (Trial Tr. 1200, Aug. 20, 2009.)

Even if they were correct, which they are not, Plaintiff's assertions regarding fracture reduction efficacy in osteopenic women do not prove that Fosamax is unreasonably dangerous. As Dr. Parisian conceded, the 1999 Fosamax label, which contains an indication for prevention of osteoporosis, states that Fosamax prevents *bone loss* in osteopenic patients, and does not state

that Fosamax reduces fractures in such patients. (Trial Tr. 1246, Aug. 20, 2009; Def. Ex. A317, at 8 (1999 Fosamax label's discussion of prevention indication).) None of Plaintiff's experts testified that Fosamax did not assist in preventing bone loss, and none of them testified that any risks of ONJ outweigh the benefits of osteoporosis prevention. There would be no credible scientific basis for such a claim, if one had been made. Plaintiff's design defect claims fail because she has introduced no evidence upon which a reasonable juror could conclude that Fosamax is unreasonably dangerous.

B. Plaintiff Presented No Evidence Of Any *Negligence* In The Design Of Fosamax.

Judgment should be entered as to the Plaintiff's claim of negligent design because Plaintiff has introduced no evidence to support any of the elements of its cause of action. A design defect claim based upon negligence requires proof (1) that Merck was negligent in the design of its product; (2) that the product contains a design defect; and (3) that the design defect was the legal cause of Plaintiff's injury. *See Nissan Motor Co. v. Alvarez*, 891 So.2d 4, 5 (Fla. Dist. Ct. App. 2004) (including these elements in jury verdict form and instructions). Where, as here, the Plaintiff has failed to prove the existence of a design defect, a claim of negligent design fails as matter of law. See *Terex Corp. v. Bell,* 689 So.2d 1122, 1123 (Fla. Dist. Ct. App. 1997) ("Because the only evidence of negligence offered against appellant at trial related to its alleged negligent design and the jury found there was no design defect, there was no other evidence to sustain its verdict.").

Even if Plaintiff had introduced evidence to show that Fosamax was defective in design, which she has not for all of the reasons discussed in § II.A, *supra*, she has presented no evidence to prove that Merck was negligent. Under Florida law, negligence requires both a foreseeable risk and a failure by the defendant to take "sufficient precautions" to avoid it. *See, e.g., Jennings*

v. BIC Corp., 181 F.3d 1250, 1257 (11th Cir. 1999) (applying negligence standards to design defect claim). Only reasonable care is required - a manufacturer need not take all possible steps or go to extreme lengths to protect foreseeable users of its products. *Id.* (citing cases).

Plaintiff has wholly failed to address these elements of proof. She has not shown that any risk of ONJ was foreseeable prior to 2003, she has not identified any reasonable precautions that Merck should have taken prior to October 2003 to prevent any alleged risk of ONJ, and she has not identified any alternative design that would have been non-defective. For each of these reasons, Merck is entitled to judgment as a matter of law with respect to Plaintiff's claim of negligent design.

III. PLAINTIFF DID NOT ESTABLISH THAT SHE HAD ONJ BEFORE OCTOBER 1, 2003.

As the Court instructed the jury, Plaintiff "contends that she developed osteonecrosis of the jaw prior to October 2003 as a result of her use of Fosamax." (Jury Charge 19.) All of Plaintiff's claims fail as a matter of law because she has presented no credible evidence that she developed ONJ prior to October 2003.[12]

- As Second Circuit and Florida cases have made plain, Plaintiff must establish the nature and cause of her injury through expert testimony. *See Wills v. Amerada Hess Corp.*, 379 F.3d 32, 46 (2d Cir. 2004); *In Re Rezulin Prods. Liab. Litig.***,** 441 F. Supp. 2d 567, 576 (S.D.N.Y. 2006); *Reaves v. Armstrong World Industries, Inc.*, 569 So.2d 1307, 1309 (Fla. Dist. Ct. App. 1990).

[12] Plaintiff must prove that she had ONJ prior to October 2003 based on her own admissions in her summary judgment papers. The Plaintiff opposed summary judgment by asserting that she had "dead bone" in her jaw in August 2002, that it was "too late to save Plaintiff's jaw" by Fall 2003, and that the alleged zone of dead bone in her jaw "remained stable" since 2003. (Summ. J. Op. & Order 19-20, 22-23, Aug. 5, 2009.) Further, Plaintiff "offered no admissible evidence demonstrating that Fosamax poses a risk to patients already suffering from ONJ" and "no reliable evidence that remaining on Fosamax after she had already developed ONJ aggravated her condition." (*Id.* 22-23.) The Court therefore held that "Plaintiff may not argue that she developed ONJ later than September 2003," and that she also could not argue that any use of Fosamax after October 1, 2003 contributed to her alleged injuries. (*Id.* 21-22.) Thus, to prevail on her claim that Fosamax caused her injuries, Plaintiff must present evidence to show both that she had BON prior to October 1, 2003 *and* that any later alleged injuries that she sustained were caused by her use of Fosamax before October 1, 2003. She has not met this burden.

- Dr. Hellstein is the sole expert witness presented by the Plaintiff to testify that Plaintiff suffered ONJ, but he could not testify with any degree of confidence, much less reasonable certainty that Plaintiff had ONJ before October 1, 2003.[13] Dr. Hellstein could only testify, in response to the Court's questioning, that Plaintiff "could" have had "stage 0 BON."[14] (Trial Tr. 720-21, Aug. 17, 2009.) Dr. Hellstein presented the same testimony on recross examination, emphasizing that he could only state that Mrs. Boles might have had "stage 0 BON," not that she did in fact, have the condition. (*Id.* 747-48; *see also id.* at 687 (agreeing that the distinction between "is" and "may be" was an important one).)[15]

- Even if Dr. Hellstein's testimony had been sufficiently definitive about "stage 0" ONJ, it would not have met Plaintiff's burden because "stage 0" ONJ is not ONJ at all. Dr. Hellstein readily admitted that "stage 0 BON" was not itself an injury. (Trial Tr. 719, Aug. 17, 2009.) Dr. Hellstein's reference to "stage 0" refers to the AAOMS staging system, (*id.* 734), under which "stage 0" is a category used to describe patients who may (or may not) develop ONJ in the future. When AAOMS adopted the "stage 0" category in 2009, AAOMS continued to require that, before a patient may be considered actually to have ONJ, the patient must have "[e]xposed bone in the maxillofacial region that has persisted for more than 8 weeks."[16] "Stage 0 BON" is merely a category of "nonspecific symptoms or clinical and radiographic abnormalities that might have been due to bisphosphonate exposure." AAOMS Position Paper at 9 (noting that "the risk of a patient with stage 0 disease advancing to a higher disease stage is unknown at this time"). As Dr. Hellstein conceded, stage 0 is not actually "having a BON injury, but being at risk for having a BON injury." (Trial Tr. 719, Aug. 17, 2009.)

- Plaintiff cannot salvage her claims by focusing on alleged jaw problems she had long after October 2003. Based upon her own admissions, Plaintiff's injuries in this case had occurred as of October 1, 2003, it was "too late" to

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[13] Plaintiff also introduced testimony by Dr. Anastasio, who treated Plaintiff in 2007, and medical records of Dr. Elwell. Neither Dr. Anastasio's testimony nor Dr. Elwell's records present any evidence that Plaintiff had ONJ prior to October 1, 2003.

[14] "BON" is the term used by Dr. Hellstein for ONJ.

[15] The remainder of Dr. Hellstein's testimony was equally speculative. For example, in referring to a medical record from April 2003, Dr. Hellstein testified that the record *could* be indicative of BON, but then admitted that it was most likely that the record merely referred to denture irritation. (Trial Tr. 707, Aug. 17, 2009.) Even Dr. Hellstein agrees that Plaintiff did not meet the "exposed bone definition of BON" until long after October 1, 2003. (*Id.* 714-15.)

[16] *See* Ruggiero, *et al.*, American Association of Oral and Maxillofacial Surgeons Position Paper on Bisphosphonate-Related Osteonecrosis of the Jaws – 2009 Update, *Journal of Oral and Maxillofacial Surgery* 67:2-12, 2009 Suppl. 1 at 9 ("2009 AAOMS Position Paper") (noting addition of Stage 0 category); *id.* at 7, Table 1.n.* (repeating that "BRONJ" continues to be defined as "[e]xposed bone in the maxillofacial region without resolution within 8-12 weeks in persons treated with bisphosphonates who have not undergone radiation therapy to the jaws").

> save her jaw by then, and her jaw "remained stable" thereafter. No witness for Plaintiff has testified that her use of Fosamax before October 1, 2003 caused her problems that allegedly arose much later. Instead, Plaintiff seeks to gloss over her admissions by presenting blanket assertions by Dr. Anastasio about Plaintiff's condition in 2007, four years after the date by which Plaintiff must show that her ONJ occurred. The Plaintiff should not be permitted to ignore the Court's ruling by presenting general claims that use of Fosamax caused her injury, because that argument invites the jury to conclude that use of Fosamax after October 1, 2003 aggravated her condition, even though she admits that her full injury had occurred by that date.

In short, Plaintiff's proof of her alleged injury is based upon rank speculation, not objective factual evidence. The furthest that Plaintiff's own expert (Dr. Hellstein) would go was to testify that Plaintiff "could" or "may" have had "stage 0 BON," (Trial Tr. 747-48, Aug. 17, 2009) while agreeing that "stage 0 BON" is not ONJ at all, but merely a set of symptoms that might indicate a risk of ONJ in the future. (*Id.* 719). Those symptoms are not unique to bisphosphonate use and do not prove that Plaintiff's jaw problems were caused by Fosamax, but are merely symptoms that "might" relate to bisphosphonate exposure. AAOMS Position Paper at 9. Such attenuated testimony provides no evidence upon which a jury reasonably could conclude that Plaintiff did in fact have ONJ prior to October 1, 2003 and that this ONJ was in fact caused by Fosamax.

In response to Merck's initial Rule 50(a) motion, the Court concluded that "viewing the evidence in the light most favorable to the plaintiff, a reasonable jury could find that the jaw problems she suffered before October 2003 was subclinical osteonecrosis of the jaw that later became exposed and developed into Stage 3 ONJ." (Trial Tr. 1631, Aug. 24, 2009.) Merck respectfully submits, however, that a jury verdict for Plaintiff on this issue must be grounded in proper expert opinion that supports Plaintiff's claims that her pre-October 1, 2003 use of Fosamax was sufficient by itself to cause the injury for which Plaintiff seeks compensation.

Plaintiff has failed to introduce any such testimony, and Merck asks the Court to enter judgment as a matter of law as to all claims for this reason.

CONCLUSION

For the foregoing reasons, the Court should enter judgment as a matter of law as to all remaining claims in this case.

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Respectfully submitted,

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